510(k) Summary

NOV 1 9 2003

K032869

Submitted By: Theodore Heise, PhD, RAC
Director of Regulatory Scientific Affairs
Cook Incorporated
750 N. Daniels Way
Bloomington, IN 47404
(812) 339-2235
September 12, 2003

Names of Device:
Trade Name: COOK CODA™ BALLOON CATHETER
Common/Usual Name: Balloon catheter
Classification Name: Percutaneous catheter

Intended Use:
The COOK CODA™ BALLOON CATHETER is intended for temporary occlusion of large vessels, or to expand vascular prostheses.

Predicate Devices:
Predicate devices are the LDOB BALLOON CATHETER (K002286) manufactured by Cook Incorporated (vessel occlusion), and the ILIAC BALLOON CATHETER (K003495) manufactured by Guidant Corporation (prosthesis expansion).

Device Description:
The COOK CODA™ BALLOON CATHETER is a 2-lumen catheter. The distal lumen extends the length of the catheter for use over a .035 wire guide. The other lumen communicates with the balloon and is used to expand and deflate it. Radiopaque bands are placed at both the distal and proximal aspects of the balloon to assist with positioning of the device under fluoroscopy. The balloon will be provided in diameters ranging from 30 to 40 mm, and in lengths ranging from 100 to 120 cm. The device is packaged in sterile, sealed double pouches.

Substantial Equivalence:
The COOK CODA™ BALLOON CATHETER is comparable with respect to technical characteristics and intended use to predicate devices in terms of 510(k) substantial equivalence.

Discussion of Tests and Test Results:
The COOK CODA™ BALLOON CATHETER underwent testing to assess biocompatibility, mechanical properties, performance characteristics, and safety. The device met the test criteria, providing reasonable assurance of device performance for its intended use and supporting substantial equivalence.

Conclusions Drawn from Tests:
The COOK CODA™ BALLOON CATHETER met the test criteria, providing reasonable assurance of device performance for its intended use and supporting substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2003

Dr. Theodore Heise
Director of Regulatory Scientific Affairs
c/o Cook Incorporated
P.O. Box 489
Bloomington, IN 47402-0489

Re: K032869
CODA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 12, 2003
Received: September 15, 2003

Dear Dr. Heise:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K032869

Device Name: COOK CODA BALLOON CATHETER

Indications for Use: The COOK CODA BALLOON CATHETER is intended for temporary occlusion of large vessels, or to expand vascular prostheses.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ashley B. Boone

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032869

Prescription Use X OR Over–the-Counter Use_____
(Per 21 CFR 801.109)